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10/825,043	04/15/2004	Mark Edward Riehl	NNI-0043	7399

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EXAMINER
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HOPKINS, CHRISTINE D

ART UNIT	PAPER NUMBER
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3735

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10/31/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/825,043

Applicant(s)

RIEHL ET AL.

Examiner

Christine D. Hopkins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-69 is/are pending in the application.
- 4a) Of the above claim(s) 16-35, 42-58 and 69 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 36-37, and 59-67 is/are rejected.
- 7) ☒ Claim(s) 11-15, 38-41 and 68 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

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### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d)

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election of claims 1-15, 36-41 and 59-68 in the reply filed on 11 September 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Boveja (U.S. Pub. No. 2001/0002441). Boveja teaches an apparatus and method for neurological therapy. Regarding claims 1-3, Boveja discloses a coil, fully capable of performing as a "TMS" coil **46** having two treatment faces (one positioned on the patient directly and the other opposing); a pulse generating device **42** that applies pulses to the coil [0051]; a sensor unit **50**, further detecting a proximity of the coil to a position at which pulses are applied and disposed between the coil and the position [0053]; and signal processing circuitry **52** that processes outputs of the sensor to provide an indication of whether the coil is properly disposed with respect to the position during

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application of pulses to the coil (Figs. 7-8, and [0052]-[0054])). Regarding claim 4, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Since the signal processing circuitry processes outputs of the sensor to determine that the coil is within energy transfer distance of the patient's interior, it is capable of determining that the coil has "valid contact" with the patient at a particular position. Regarding claims 5 and 7-8, indication of proper placement of the coil is provided by a "display" or LED 140 or an alarm [0054]. With respect to claim 6, if the proximity distance drops off such that the coil is not within a therapeutic range, an alarm indicates failure noting improper contact. Further regarding claim 7, since applicant has not provided a specific definition for a "pressure map" it is understood that the display or LED taught by Boveja is believed to anticipate such since it is a visual indication.

4. Claims 59-66 are rejected under 35 U.S.C. 102(e) as being anticipated by Tanner et al. (U.S. Pub. No. 2004/0193002). Tanner et al. (hereinafter Tanner) teach a system for providing transcranial magnetic stimulation. Regarding claim 59, Tanner discloses a method for providing TMS treatment to a patient comprising the steps of detecting proximity of a TMS coil [0015] to a position at which pulses are to be applied to the TMS coil [0014] and providing an indication of whether the coil is properly disposed with respect to the position via automatic movement of the induction device to the particular position [0018].

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According to claims 60-63, a position detection device or sensor is disposed between a coil having a treatment face (Fig. 5) and the location of interest, pulses are applied by the stimulation device, and a proximity of the coil to a valid position on the patient is determined ([0019]-[0020]). Further regarding claim 62, the opposing side of the induction device 1 (Fig. 5) is considered to be the "second treatment face" since the device operates as a whole to locate a particular position on the patient.

Regarding claims 64-66, a display visually indicates to an operator whether the coil is properly positioned at a position on the patient and which direction the coil may be moved in order to re-locate to the position of interest if necessary. The simulation and spatial resolution on the display is considered to be a "pressure map" indicating whether or not the coil is at an optimal location ([0017] and [0021]).

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 9 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boveja (U.S. Pub. No. 2001/0002441). Boveja discloses the invention as claimed, to include a substrate disposed between a coil and a position of a patient and at least one sensor disposed on the substrate to detect proximity of the coil to a position; however Boveja does not disclose expressly that the sensor is disposed in a flexible substrate.

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Instead, Boveja indicates that the sensor or sensing unit contained in the coil is taped firmly to the skin for efficient energy transfer to occur [0051]. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use a flexible substrate because Applicant has not disclosed that a flexible substrate provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art would have expected Boveja's stimulation system and applicant's invention, to perform equally well with either the substrate taught by Boveja or the claimed flexible substrate because both would perform the same function of enabling conformation to the skin of a patient. Therefore, at the time of the invention it would have been prima facie obvious to modify Boveja to obtain the invention as specified in claims 9 and 36 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Boveja.

7. Claims 10 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boveja (U.S. Pub. No. 2001/0002441) in view of Grove et al. (U.S. Pub. No. 2004/0167592). Boveja discloses the invention as claimed, see rejection supra; however Boveja does not disclose a membrane switch. Grove et al. (hereinafter Grove) teaches an apparatus which employs a therapeutic energy source and one or more switches placed in contact with a person's skin. Regarding claims 10 and 37, Grove discloses that a contact sensor, as similarly taught by Boveja, may be a type of membrane switch such that when the apparatus is pressed against the skin, the membrane switch closes, indicating the initiation of pulsing therapy [0016]. Therefore,

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at the time of the invention it would have been obvious to one of ordinary skill in the art to have incorporated membrane switches as disclosed by Grove into a therapeutic pulsing apparatus as taught by Boveja for indicating contact with a patient's skin and subsequently initiating therapy.

Moreover, the combination of Boveja in view of Grove discloses the invention as claimed, see rejection supra; however the combination does not disclose expressly that the membrane switch comprises respective conducting films separated by a dielectric layer. Instead, Boveja in view of Grove discloses that a contact sensor may be a type of membrane switch such that when the apparatus is pressed against the skin, the membrane switch closes, indicating the initiation of pulsing therapy [0016]. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use a membrane switch comprising respective conducting films separated by a dielectric layer because Applicant has not disclosed that such a membrane switch provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art would have expected Boveja in view of Grove's stimulation system and applicant's invention, to perform equally well with either the membrane switches taught by Boveja in view of Grove or the claimed membrane switch comprising respective conducting films separated by a dielectric layer because both would perform the same function of sensing positioning and contact with the skin of the patient. Therefore, at the time of the invention it would have been prima facie obvious to modify Boveja in view of Grove to obtain the invention as specified in claims 10 and 37 because such a modification would have been considered a mere



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design consideration which fails to patentably distinguish over the prior art of Boveja in view of Grove.

8. Claim 67 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tanner et al. (U.S. Pub. No. 2004/0193002) in view of Boveja (U.S. Pub. No. 2001/0002441). Tanner discloses the invention as claimed, see rejection supra; however Tanner fails to disclose a sound generator indicating that the coil is properly positioned. Boveja teaches an apparatus and method for neurological therapy. Regarding claim 67, Boveja teaches that if the proximity distance drops off such that the coil is not within a therapeutic range, an alarm indicates failure noting improper contact. Tanner likewise discloses a display and subsequent movement of a robotic arm as an indication of proper alignment. Therefore, at the time of the invention it would have been obvious to one having ordinary skill in the art to have incorporated a sound generator as suggested by Boveja to a TMS apparatus as taught by Tanner in order to indicate proper placement of a TMS coil for subsequent treatment to a particular area of the cranium.

#### ***Allowable Subject Matter***

9. Claims 11-15, 38-41, and 68 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The following is a statement of reasons for the indication of allowable subject matter: regarding claim 11, the prior art of record does not teach or fairly suggest that the conductive films have a sufficient resistance so as to reduce eddy currents. Regarding claim 12, the prior art of record

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does not teach or fairly suggest that the signal processing circuitry comprises a debounce circuit and an artifact detection and removal circuit. With respect to claim 13, the prior art of record does not teach or fairly suggest non-conductive microslides applied to the flexible substrate so as to amplify compression of the membrane switches. Regarding claims 14-15, the prior art of record does not teach or fairly suggest that the membrane switches comprise resistive strips that provide an output voltage that varies with position of contact on the membrane switches.

Regarding claim 38, the prior art of record does not teach or fairly suggest that the conductive films have a sufficient resistance so as to reduce eddy currents. With respect to claim 39, the prior art of record does not teach or fairly suggest non-conductive microslides applied to the flexible substrate so as to amplify compression of the membrane switches. Regarding claims 40-41, the prior art of record does not teach or fairly suggest that the membrane switches comprise resistive strips that provide an output voltage that varies with position of contact on the membrane switches.

Regarding claim 68, the prior art of record does not teach or fairly suggest placing a plurality of sensors in or on a flexible substrate and placing the flexible substrate between a TMS coil and the position of interest, according to claim 60, to determine if the coil is properly positioned with respect to the position during TMS therapy.

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***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine D. Hopkins whose telephone number is (571) 272-9058. The examiner can normally be reached on Monday-Friday, 7 a.m.-3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christine D Hopkins  
Examiner  
Art Unit 3735